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Anthrax Preparedness: HHS Progress

Statement of
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Good afternoon, Mr. Chairman, Mr. Kucinich and Subcommittee members. I am Gerald Parker, Principal Deputy to the Assistant Secretary for Public Health Emergency Preparedness, Department of Health and Human Services (HHS). I appreciate the opportunity to share with you information on the Department's efforts to improve our nation's preparedness for the threat of anthrax and to detail the substantial progress that has been made since the anthrax attacks of October 2001.

The events of October 2001 made it very clear that bioterrorism is a serious threat to our Nation and the world. Defending against threats such as anthrax is a top priority for the Bush Administration. The President made clear in his "Biodefense for the 21st Century" that the United States will continue to use all means necessary to prevent and protect against biological weapon attacks perpetrated against our homeland and our global interests. His policy provides a blueprint that integrates the sustained efforts of the national and homeland security, medical, public health, intelligence, diplomatic, and law enforcement communities. The essential pillars of the policy are: Threat Awareness, Prevention and Protection, Surveillance and Detection, and Response and Recovery. While HHS has a wide range of responsibilities in all domains, HHS has a leadership role in medical and public health missions.

I will focus my remarks this afternoon on critical components of HHS' medical and public health mission: Medical countermeasure development and acquisition

and specifically those designed to prevent and treat anthrax. I am pleased to have my colleague, Dr. Richard Besser, from the Centers for Disease Control and Prevention (CDC) here with me on the panel today and will defer to him to discuss other critical aspects of HHS' anthrax preparedness and response mission including surveillance and detection activities and coordination with State and local partners in the delivery and distribution of medical countermeasures. HHS and CDC are working closely with state and local public health officials on public health and bioterrorism preparedness and, including the FY07 budget request, has invested nearly $8 billion to States and territories through cooperative agreements since 2001.

The mission of the Office of Public Health Emergency Preparedness (OPHEP), in keeping with the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, the Project BioShield Act of 2004 and the President's "Biodefense for the 21st Century" is far reaching and encompasses a myriad of responsibilities. My remarks this afternoon will focus on the progress we have made with the development and acquisition of Medical Countermeasures for the anthrax threat. However, it is important to recognize that public health threats and emergencies can ensue from multiple other causes, both naturally-occurring and man-made, and that many of the preparedness activities we are pursuing in OPHEP will have cross-cutting value. Bioterrorism preparedness is not an insular activity for HHS but rather a critical component integrated within an all-hazards readiness program. To ensure the synchronization of HHS' emergency

preparedness efforts, including the development and acquisition of medical countermeasures, OPHEP coordinates HHS-wide activities and serves as the principal point of contact at HHS for other Federal agencies and Departments.

Medical Countermeasure Development

Development, acquisition and deployment of safe, effective medical countermeasures to mitigate illness and death in the event of an anthrax attack are top priorities for HHS. Although much remains to be done, we have made substantive progress in building our Strategic National Stockpile from where it was pre-9/11to what we have available today. Antibiotics remain a cornerstone of our response strategy to anthrax and demonstrate the dramatic improvements to our readiness. In December 2000 we only had enough 60-day regimens to provide post-exposure prophylaxis for approximately 137,000 people. Today we could provide this antibiotic regimen to over 40 million individuals. The research, development and acquisition of an appropriate armamentarium of medical countermeasures is a critical element of the response and recovery component of the President's "Biodefense for the21st Century" and HHS leads these U.S. Government efforts and continues to make significant gains, particularly with regard to implementation of the Project BioShield Act of 2004 ("Project BioShield"). The acquisition and ready availability of medical countermeasures, such as antibiotics, antivirals, monoclonal and polyclonal antibodies against anthrax, and vaccines to protect against exposure are essential to our Nation's

preparedness and response capabilities in the face of the threat posed from anthrax.

Although anthrax is not transmissible from person-to-person, an attack involving the aerosol dissemination of anthrax spores, particularly in an urban setting, is considered by public health experts to have the potential to cause catastrophic damage. The potential for large-scale population exposure following aerosol release of anthrax spores, the threat demonstrated by the anthrax letters, and our knowledge that anthrax had been weaponized by state-actors, highlighted the nature of the threat. The Secretary of Homeland Security determined that anthrax poses a Material Threat to the Nation. Because untreated inhalation anthrax is usually fatal, the Secretary of HHS identified anthrax as a significant threat to public health.

The Strategic Approach to Addressing Medical Countermeasure Gaps

The initial focus of our efforts to protect the Nation was aimed largely at those threats that could do the greatest harm to the greatest number of our citizens. Among biological threat agents, anthrax is widely recognized as having the greatest potential to cause catastrophic harm. A sense of urgency has pervaded our efforts and we have defined new ways of doing business. Our new national security environment demands accelerated product development timelines and

new paradigms of interactions between industry and government with increased risk-sharing and enhanced intra-governmental collaboration.

Today we have a diverse and continually growing stockpile of medical countermeasures to respond to an anthrax attack. First, as our front line of response we have antibiotics to provide post-exposure prophylaxis for over 40 million people. Second, we have acquired 5 million doses of the vaccine anthrax vaccine adsorbed (AVA), and have recently modified the contract for 5 million additional doses within a year. Third, we are aggressively developing a next generation anthrax vaccine and have moved forward with the acquisition of 75 million doses. Fourth, we are increasing our stockpile of anthrax antitoxins to treat the toxemia associated with anthrax disease.

Developing, Acquiring and Deploying Priority Medical Countermeasures

The National Institutes of Health (NIH) is shaping and executing an aggressive biodefense research and development program to advance new and improved medical countermeasures, including next-generation vaccines and therapeutics for anthrax. Additionally, NIH supports the development of critical biodefense research infrastructure such as biocontainment facilities and the product development tools, such as animal models, required to demonstrate efficacy in support of a regulatory strategy toward Food and Drug Administration (FDA) approval. Most significantly, building on a substantial research base from the Department of Defense, the National Institute of Allergy and Infectious Diseases

(NIAID) in NIH has played a crucial role in the development of the next generation anthrax vaccine.

The Strategic National Stockpile (SNS), managed by CDC, contains large quantities of medicine and medical supplies to protect the American public in the event there is a public health emergency severe enough to exhaust local supplies or warrant specific medical countermeasures held only in the SNS. Portions of the SNS are configured in 50-ton, 12-Hour Push Packages that contain supplemental medicine and medical supplies designed to be deployed rapidly and used in mass casualty incidents. These packages can be delivered to any point in the country within 12 hours of a Federal decision to deploy. Each state is required to develop plans to receive and distribute SNS medicine and medical supplies to local communities as quickly as possible in the event of a deployment SNS staff assist state and local planners with the receipt, staging, storage, distribution and dispensing of SNS assets. In the event of an anthrax attack the antibiotics, vaccines and antitoxins held in the Strategic National Stockpile, will be critical assets in efforts to mitigate loss of life and illness.

Project BioShield

The Project BioShield Act of 2004 (P.L.108-276) ("Project BioShield") is a critical part of a broader strategy to defend America against the threat of weapons of mass destruction. It provides HHS with several new authorities to speed the research, development, acquisition, and availability of medical countermeasures to defend against chemical, biological, radiological and nuclear (CBRN) threats.

In exercising the procurement authorities under Project BioShield, HHS has launched acquisition programs to address each of the four threat agents deemed to be Material Threats to the U.S. population by DHS [*Bacillus anthracis* (anthrax), smallpox virus, Botulinum toxins, and radiological/nuclear agents]. HHS has already used the Special Reserve Fund (SRF) to award two contracts for vaccines against anthrax, including a recent acquisition of 5 million additional doses of the licensed anthrax vaccine adsorbed (AVA) vaccine, and will soon acquire anthrax therapeutics for the SNS.

The focus on medical countermeasures for anthrax is a reflection of the priority that the threat of anthrax has been given by HHS. HHS is pursuing a comprehensive medical countermeasure strategy involving antibiotics, vaccines and antitoxins to address the threat of anthrax. We have already obligated over $1.1 billion for anthrax vaccines under Project BioShield and that investment will increase substantially once pending action on the anthrax therapeutics acquisition program is executed.

The FDA has approved antibiotics for post-event treatment of anthrax exposure, and these antibiotics are at the front line of our comprehensive preparedness strategy. During FY 2004 and 2005, CDC purchased a large number of anthrax antibiotics and the SNS now holds enough to provide 60-day regimens for post-exposure prophylaxis to approximately 41.5 million people. In addition, the SNS

holds intravenous antibiotics to treat approximately 831,000 symptomatic anthrax patients.

HHS is also pursuing the acquisition of therapeutic antitoxins to treat symptomatic anthrax patients. Neither vaccine nor antimicrobials are able to treat the toxemia that occurs as anthrax disease progresses. Thus, despite the current supply of antimicrobials in the SNS, and current and ongoing acquisitions for anthrax vaccines, an important gap remains in our defensive strategy against anthrax. An additional gap in our defensive strategy against anthrax is the lack of an intervention against an anthrax strain engineered to be resistant to currently available antimicrobials. To address these gaps, HHS has been pursuing acquisition of immune-based products that target the anthrax toxins, as well as other novel antitoxin interventions, that will be stockpiled as an adjunct to the antibiotic therapy for symptomatic patients. A Request for Proposals for acquisition of such products was released in 2004 and awards will be made in 2006. In addition, NIH continues to support the development of these medical countermeasures and future requirements for these products are being considered by the WMD Medical Countermeasures Subcommittee based on a material threat assessment conducted by DHS and the results of medical consequence modeling.

In addition to these anthrax medical countermeasures, anthrax vaccines are also being pursued by HHS. Anthrax vaccines are useful in certain conditions:

- They provide pre-exposure protection of individuals at increased risk of exposure to anthrax, such as laboratory workers, manufacturers and product development workers, and certain first responders.
- They potentially provide additional protection in a post-exposure setting, when used in combination with antibiotics, and as a strategy to potentially reduce the currently recommended 60-day duration of antibiotic treatment. This extended duration of antibiotic treatment poses formidable compliance challenges.
- They provide protection in the event of antimicrobial resistance.
- They provide relatively long-term protection and enable worker re-entry into areas that have been exposed to anthrax spores, for example by remediation workers.

Due to limitations inherent in the currently available anthrax vaccine, there is consensus in the scientific community about the need to develop and acquire a next-generation anthrax vaccine using 21st century technologies. An assessment of developing technologies was undertaken by HHS experts in the fall of 2001 and the decision was made that there was a sufficient scientific foundation, including a detailed understanding of the pathogenesis of anthrax and how anthrax vaccines provide protective immunity, to support the aggressive development of a next generation vaccine consisting of recombinant protective antigen (rPA). The research undertaken to develop this vaccine, spanning more

than a decade, was conducted in large part by the United States Army Medical Research Institute of Infectious Diseases at Fort Detrick, Maryland. The urgency of the need for a next-generation vaccine with improved manufacturing processes that would enable more robust characterization and consistency was also articulated in a 2002 Institute of Medicine report.

HHS defined a three-stage development and acquisition strategy with open competition for awards at each stage. The early and advanced development programs were supported by the National Institute of Allergy and Infectious Diseases (NIAID) with contract awards in September 2002 and 2003, respectively. These were milestone-driven contracts with well-defined deliverables including the manufacture of clinical-grade vaccine, the conduct of Phase I and Phase II clinical trials, and consistency lot manufacturing of vaccine. Large-scale manufacturing capacity would be required to support the civilian requirement for this medical countermeasure, which was defined by the WMD Subcommittee to be the initial protection of up to 25 million persons. Senior officials from several Departments of the USG evaluated acquisition options to achieve this requirement and, in the fall of 2003, approved the decision to pursue the acquisition of rPA anthrax vaccine.

An evaluation of the NIAID rPA anthrax vaccine development program indicated that it was robust enough to suggest that the rPA vaccine could become a licensed product within 8 years. In March 2004, the acquisition program for this

vaccine, under the direction of my office, was launched using the Special Reserve Fund created in the FY 2004 DHS appropriations bill. Utilizing a robust technical and business evaluation process, we reviewed multiple proposals and negotiated a contract for the acquisition of 75 million doses of the vaccine (anticipating a three-dose regimen). Using a milestone and deliverables approach similar to the ACAM2000 smallpox vaccine development and acquisition program, and the rPA anthrax vaccine development contracts at NIAID, the rPA vaccine BioShield acquisition contract lays out an ambitious program for the production of this vaccine. In accordance with Project BioShield, a critical aspect of this acquisition contract is the fact that no payment for product is made until a usable product is delivered to the SNS. On November 1, 2005, VaxGen announced that it anticipated beginning delivery of its rPA anthrax vaccine to the U.S. Government in the fourth quarter of 2006. The company had previously planned to initiate deliveries during the first half of this year. HHS has recently modified the contract with VaxGen and established a new delivery schedule. We now anticipate initial delivery by late 2008 and completion of the delivery of 25 million doses of the rPA anthrax vaccine to the SNS no later than October 2009. Delays in accelerated development programs are not unexpected or unprecedented. For example, while ACAM2000 smallpox vaccine program experienced slippages in the projected timeline, the program was ultimately successful, the Federal government received the full delivery required under the contract, and the nation is now better prepared.

HHS maintains a commitment to develop a next-generation rPA anthrax vaccine. In addition to this acquisition contract, HHS continues, through the National Institute of Allergy and Infectious Disease (NIAID), to support funding for rPA anthrax vaccine development with contracts to VaxGen, Inc. and Avecia Biotechnology

While awaiting delivery of the rPA anthrax vaccine to the SNS, HHS has moved forward to meet immediate anthrax vaccine requirements through the acquisition of 10 million doses of AVA under the Project BioShield authorities. A contract for 5 million doses was awarded in May 2005. Delivery of this product to the SNS began soon after contract award and was completed in February 2006. Last week, HHS modified the contract and purchased an additional 5 million doses of AVA for the Strategic National Stockpile, increasing our total investment in AVA to $243 million.

Conclusion

In closing, I must re-emphasize that amongst the list of potential threats, we all recognize anthrax as a top priority. HHS efforts and investments in the 4½ years since the anthrax attacks in the fall of 2001 reflect that priority. Our investments and efforts have done much to improve our preparedness and strengthen our response capabilities. We will continue to develop our strategic approach to further combat this threat. HHS and its agencies including NIH, CDC, and FDA,

have a clear mandate from President Bush and Congress to continue to lead the charge in this arena. We have already made important strides and will continue to work to address the obstacles identified. Mr. Chairman, I look forward to working with you and members of the Subcommittee to address the challenges of anthrax preparedness.

I will be happy to answer any questions you may have.